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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,094

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Katsuyoshi Nagao

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04/23/2010

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EXAMINER

MARCETICH, ADAM M

ART UNIT

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3761

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/554,094	Applicant(s) NAGAO ET AL.	
	Examiner Adam Marcetich	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,11-13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,11-13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>18 February 2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. PCT/JP/2004/005547, filed on 19 April 2004 has been received.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meierhoefer (US 4502616) in view of Itoh; Takurou et al. (US 6042906) in view of Ding; Yuan-pang Samuel et al. (US 6255396).
5. Regarding claim 1, Meierhoefer discloses an ampoule comprising:

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6. a flexible container body (column 3, lines 56-65 and Fig. 3, vials or ampoules 12);
7. containing a drug solution (col. 3, lines 60-65, Fig. 6, medicated treatment liquid 14);
8. a fusion-bonded portion which seals a mouth of the container body (column 4, lines 25-36 and Fig. 3, seal 44);
9. a holder tab connected to the fusion-bonded portion for wrenching off the fusion-bonded portion (column 4, lines 25-36 and Fig. 3, key 26); and
10. a plastic or polymer capable of preventing drug permeation (column 3, lines 56-65, moldable plastic).

11. Meierhoefer discloses the invention substantially as claimed, see above.

However, Meierhoefer discloses at most a single layer and therefore lacks three or more layers as claimed [1].

12. Itoh discloses a multi-layer plastic container (col. 1, lines 6-13), comprising:
13. at least three layers, the intermediate layer comprising a cyclic olefin (col. 3, lines 37-44);
14. a functional layer having a drug permeation preventing capability (col. 5, lines 31-41, cyclic olefin layer providing excellent gas barrier);
15. an intermediate layer within the claimed thickness range (cols. 16-17, lines 65-5, ratio of intermediate layer to total thickness between 1:99 and 30:70 overlapping claimed range of 11.8 to 35.3%).
16. Examiner interprets the relative intermediate layer thickness as a result-effective variable, subject to experimentation and testing. A result-effective variable is a

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parameter which achieves a recognized result. These results are obtained by the determination of optimum or workable ranges of said variable through routine experimentation. The property of intermediate layer thickness forms a container with effective gas barrier properties through routine experimentation.

17. Here, Itoh demonstrates that the claimed range is also effective in preventing materials from diffusing through a barrier layer (col. 19, lines 11-14, multi-layer plastic container effective to prevent diffusion of fragrant or alcohol-containing substances). In other words, Itoh shows that the claimed thickness range also prevents diffusion of volatile substances. Also, Itoh demonstrates a container having multiple intermediate layers (col. 17, lines 18-27, especially lines 26-27, additional adhesive resin / AD layers). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the intermediate layer thickness in order to form an effective gas barrier. See MPEP 2144.05(II)(A,B). Also see in re Boesch and Slaney, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

18. Meierhoefer and Itoh disclose the invention as substantially claimed, including the intermediate polycycloolefin layer of Itoh. However, Meierhoefer and Itoh lack a polyolefin-polycycloolefin blend in the claimed ratio [1]. Ding discloses a container for medical fluids (col. 1, lines 13-28, col. 3, lines 51-63, Fig. 1, I.V. container 12), comprising:

19. a blended polymer layer (col. 5, lines 16-34, two-component blend), composed of blends of:

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20. 20 to 50 wt% of polyolefin (col. 5, lines 29-34, ethylene or propylene in 65-1% range); and

21. 50 to 80 wt% of polycycloolefin (col. 5, lines 16-25, cyclic olefin / COC in 35-99% range).

22. Ding provides a recyclable polymer blend compatible with medical solutions (col. 1, lines 33-37, 46-60). Additionally, Ding discloses that the polyolefin-polycycloolefin blend is especially suited for solvent bonding (cols. 6-7, lines 65-7, solvent bonding). One would have been motivated to modify Meierhoefer and Itoh with the polyolefin-polycycloolefin blend as taught by Ding, since Meierhoefer calls for forming a container, filling it with fluid and then sealing it (col. 3, lines 60-65, col. 4, lines 25-36). A polymer blend suited for solvent blending allows the vials to be manufactured using a conventional technique, as called for by Meierhoefer. Therefore it would have been obvious to modify Meierhoefer and Itoh with the specific polymer blend of Ding in order to provide a polymer suited for rapid manufacture, namely solvent bonding.

23. Meierhoefer teaches that the vials or ampoules 12 comprise a polymer (col. 3, lines 56-65), but is silent as to the method of manufacture, namely being "integrally molded." The limitation of being "integrally molded" is treated as a product by process limitation; that is, a container that is made by molding. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113. Thus,

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even though Meierhoefer is silent as to the process used to form the vials or ampoules 12, it appears that the product as taught by Meierhoefer would be the same or similar as that claimed; especially since both applicant's product and the prior art product comprise a polymer and are mass-produced.

24. Regarding claim 3, Meierhoefer discloses the invention substantially as claimed, see above. However, Meierhoefer lacks an additive as claimed [3]. Itoh discloses:

25. a layer provided as other than an innermost layer and composed of a material containing at least one additive selected from the group consisting of colorants or UV absorbing agents (col. 6, lines 48-57, col. 15, lines 21-30, especially lines 27-30, Fig. 4, non-cyclic olefin resin in inner/outer layers 21, 25 comprising blending agents); and

26. a layer provided inward of the additive-containing layer and having a drug permeation preventing capability (col. 5, lines 31-41, col. 6, lines 48-57, Fig. 4, intermediate layers 22, 24, cyclic olefin layer providing excellent gas barrier).

27. Here, Itoh blocks UV rays while preventing a medicine from exiting the container. This preserves medicine from degrading when exposed to light, or by diffusing through the container. Therefore it would have been obvious to modify Meierhoefer with the additives in layers as taught by Itoh in order to preserve medication.

28. Regarding claim 11, Meierhoefer discloses an ampoule sequence including a plurality of ampoules connected to one another via severable thin wall portions (column 4, lines 45-49 and Fig. 1, separation strip 36).

29. Regarding claim 12, Meierhoefer discloses the invention as substantially claimed, including a volume of 0.5 to 20mL (col. 5, lines 1-4, 0.5 ml volume overlapping claimed

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range of 0.5 to 20mL). However, Meierhoefer is silent regarding steam permeation and drug absorption/adsorption preventing capabilities. Itoh discloses a functional layer, namely the polycycloolefin intermediate layer as discussed for claim 1 above.

Additionally, the polycycloolefin intermediate layer of Itoh blocks water vapor (col. 5, lines 42-54, water barrier properties of cyclic olefin copolymers having Tg above 60C).

A layer that blocks water as described by Itoh also blocks steam, especially when Tg is above 60C. Regarding rationale and motivation to modify Meierhoefer in view of Itoh, see claim 1 above.

30. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louviere (US 6254376) in view of Itoh; Takurou et al. (US 6042906) in view of Ding; Yuan-pang Samuel et al. (US 6255396).

31. Regarding claim 13, Louviere discloses a production method for a drug solution filling plastic ampoule comprising the steps of:

32. molding a container body by holding a tubular parison between lower split mold pieces (column 5, lines 57-62 and Fig. 1, core pins 68, 70 and slide inserts 26, 28; column 9, lines 47-65). Louviere discloses forming a hollow plastic article (column 9, lines 31-34) therefore it naturally follows that that Louviere has a step of forming a void in a parison.

33. A parison is defined as a partially shaped mass of molten glass (online dictionary, "parison"). Applicant has not further defined the term "parison" in the

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specification, therefore it is given its plain meaning. Liquidized plastic reasonably meets the definition of “parison” in the context of plastic molding.

34. Louviere discloses a step of filling a drug solution in a container body (column 10, lines 28-37).

35. Louviere substantially discloses holding a mouth of a container body between upper split mold pieces to form a fusion-bonded portion which seals the mouth of the container body and a holder tab which is connected to the fusion-bonded portion to be used for wrenching off the fusion-bonded portion (column 9, lines 34-41 and Fig. 8, rectangular extension top 240A and nearby neck).

36. Louviere discloses the invention substantially as claimed. However, Louviere lacks a parison having three or more layers as claimed [13]. Examiner cites Itoh and Ding to remedy the deficiencies of Louviere, namely:

37. the three layers of Itoh; and

38. the polyolefin-polycycloolefin blend of Ding.

39. See discussion of claim 1 above regarding rationale and motivation to modify Louviere in view of Itoh and Ding.

40. Regarding claim 15, Louviere discloses the invention substantially as claimed, see above. However, Louviere lacks an additive as claimed [15]. Examiner cites Itoh as teaching an additive; see discussion for claim 3 above regarding rationale and motivation to modify Louviere in view of the colorant or UV absorbent of Itoh.

Response to Arguments

41. Applicant's arguments filed 22 March 2010 with respect to the rejection(s) of claim(s) 1, 3-7, 11-13 and 15 under 35 USC § 103 over Meierhoefer, Pfeiffer, Itoh and Louviere have been fully considered and are persuasive. Therefore, the rejection is withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 USC § 103 over Meierhoefer, Itoh, Ding and Louviere.

42. Claim 1 is amended to require an intermediate layer having blends of polyolefin and polycycloolefin, consistent with examples 4-5 in the specification (p. 41, table 1). Applicant notes that Pfeiffer lacks an intermediate layer composed of the claimed polyolefin-polycycloolefin blends in the claimed ratios [1]. Applicant finds that Pfeiffer requires a cycloolefin polymer (COP)-containing layer, to contain at least 50% by weight, preferably 60-99% by weight, of a polyolefin, and therefore cannot be modified to overlap the claimed range of 50 to 80 wt% of polycycloolefin. Applicant asserts that Pfeiffer and Itoh fail to remedy the deficiencies of Louviere as discussed for claim 1. Examiner instead cites Ding as teaching the claimed range of 50 to 80 wt% of polycycloolefin in the new grounds of rejection.

Conclusion

43. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ◆ Ling, Michael T.K. et al. US 20020132077
- ◆ Christopherson, Roy et al. US 20020160135
- ◆ Kakemura; Toshiaki et al. US 5968616

44. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

45. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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46. Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Adam Marcetich

Tel 571-272-2590

Fax 571-273-2590

47. The Examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

48. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

49. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/

Examiner, Art Unit 3761

/Leslie R. Deak/

Primary Examiner, Art Unit 3761

21 April 2010